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| 09/623,485 | 09/15/2000 | Nobuya Sato | 197129US0PCT | 7267 |
| 22850 | 7590 | 05/25/2004 | EXAMINER | |
| OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | GHALI, ISIS A D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1615 | |
| DATE MAILED: 05/25/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,485

Applicant(s)

SATO ET AL.

Examiner

Isis Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7-10 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-10 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's amendment and request under 1.114, both filed 03/29/2004.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/29/2004 has been entered.

Specification

2. The use of the trademarks: "Mirason 11P", "Ultzex 15100", "DFDB 9042", "Affinity EG8200", "Evaflex P2807", "Acryft CM4013", "KS357P", "PF-814", "F569D", and "Tafmer BL2481" have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

3. Claim 3 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 3 recites "a polyolefin resin", while claim 1 recites specific polyethylene and polypropylene, and not all the polyolefin resins.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3, 7-10, 24-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain thermoplastic resins including the polyolefins and EVA copolymers and certain natural oils that are listed in tables 1-4, does not reasonably provide enablement for all the other thermoplastic resins and oily ingredients claimed in claims 1 and 24. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re*

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Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is sheet comprising at least one thermoplastic resin, active agent and oily ingredient.

The breadth of the claims: The claims are very broad. The claims encompass wide classes of each ingredient. The thermoplastic resin includes polyolefins, acrylics, polyesters, polyvinyl resins, polystyrenes, etc. The active agents include local and systemic drugs. The oily ingredients include all the natural fats and natural oils and also all the monoesters and diesters that can encompass all the fatty acids and fatty alcohols and their esters, as well as monoesters and diesters of any acids or alcohol.

The state of the prior art: The state of the art recognized sheet comprising polyolefin, hydrocarbon and UV absorbers, see US 3,725,520. The state of the art also recognized layer comprising EVA copolymer, glycerin and anti-wrinkling agent, US 6,180,133.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The specification provides no guidance, in the way written description, on sheet comprising each of the ingredients in

terms of different combinations. The specification enabled the thermoplastic resins and natural oils listed in tables 1-4, but not each of the claimed ingredients. It is not obvious from the disclosure of polyolefins and EVA copolymer that other thermoplastic resins will work. It is not clear from the disclosure of few natural oils listed in tables 1-4 that all the claimed oils and fats and fatty acids and alcohols and their esters will work. Further it is not clear from the disclosure that any of the claimed active ingredients will work. In *re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." The article "Broader than the Disclosure in Chemical Cases," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of guidance from the specification and from the prior art with regard to sheet comprising each of the three claimed components in different combinations makes practicing the claimed invention unpredictable in the terms of sheet comprising different combinations from each component.

The presence or absence of working examples: The specification enabled only the combination of the polyolefins with the few natural oils as in tables 1-4, not even any of the active agents. No working examples to show each of the components in the different combinations of the claimed ingredients. Therefore, the specification has enabled only the thermoplastic resins and natural oils listed in tables 1-4, but not all the claimed thermoplastic resins and oily ingredients, nor any of the active agents.

The quantity of experimentation necessary: Therefore, the practitioner would turn to trial and error experimentation to practice the instant sheet comprising three components without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 10, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1 and 24, the expression "ameliorating agent", does not set out the metes and bounds of the claims. Recourse to the specification does not define the expression to clarify the difference between "ameliorating agent" and any of "anti-inflammatory agent, cooling agent and warming agent", because these agents are ameliorating agents. The expressions "hair-growth regulating agent", "hair growing agent", and "hair nourishing agent" do not set out the metes and bounds of the claims.

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Recourse to the specification does not define the expressions to clarify the difference between these agents because they overlap in definitions and functions. Clarification is requested.

Further, broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. In the present instance, claims 1 and 24 recite the broad recitations "monoester" and "diester" and the claims also recite "fatty acid ester and fatty alcohol ester" which are the narrower statement of the range/limitation.

Regarding claim 10, the claim recites the acronyms "EPDM" and "EPM" that do not set out the metes and the bounds of the claim because the specification does not define the acronyms.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3,725,520 ('520).

The present claims 1 and 24 read as sheet comprising 100 parts of at least one thermoplastic resin, 0.01 to 200 parts of active agent and oily ingredient.

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US '520 disclosed a film or sheet comprising 100 parts of at least one thermoplastic resin; 20-50 parts of agents selected from alumina and titanium oxide that are UV absorbers as disclosed by applicant; and hydrocarbons that claimed by applicant as oily ingredient (abstract; col.1, lines 15-28; col.4, lines 10-17, 27-29; col.5, lines 17-23; col.12, lines 26-30). The thermoplastic resin is selected from polyolefin groups such as polyethylene and polypropylene, polyvinyl resin such as polyvinyl chloride and polystyrene (col.4, lines 10-17). The reference disclosed method of making the sheet comprising the steps of mixing the ingredients, and molding into the desired sheet (col.2, lines 23-30, 33). The sheet disclosed by the prior art that has the same ingredients in the same amounts will inherently has the same physical properties including the modulus.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-3, 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,180,133 ('133).

US '133 teaches a matrix layer, that reads on sheet, comprising EVA copolymer, moisturizing agent, and glycerin (col.6, lines 33, 46, 55-57). The layer has modified adhesiveness to the skin (abstract; col.36-45).

The reference differs from the claimed invention in not teaching the amounts of each ingredient or the claimed modulus and thickness of the sheet.

The claimed amounts and thickness do not impart patentability to the claims, absent evidence to the contrary. Adjusting the amounts of different ingredient is within the skill in the art in order to achieve specific properties of the sheet according to intended use.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide sheet comprising thermoplastic resin, active agent, and oily ingredient as disclosed by the reference, and adjust the amounts of different ingredient to achieve the desired physical properties required for a specific intended use, motivated by the teaching of the reference that this particular layer is adapted for prolonged use, with reasonable expectation of having a sheet with the desired properties of adhesiveness and stretchability.

12. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '520 or US '133 in view of US 6,022,550 ('550).

The teachings of the references are discussed above, however, the references do not teach the thermoplastic elastomer claimed in claims 7-10.

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US '550 teaches a sheet having shape-memory effect and excellent chemical resistance comprising polystyrene-based elastomer comprising hard styrene phase and flexible phase comprising diene compound such as polybutadiene (abstract; col.3, lines 56-61; col.4, lines 1-18, 26-33; col.5, lines 55-59).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide sheet comprising thermoplastic resin, active agent, and oily ingredient as disclosed by any of US '520 or US '133, and add the thermoplastic elastomer having hard styrene phase and flexible polybutadiene phase as disclosed by US '550, motivated by the teaching of US '550 that the sheet comprising this elastomer has shape-memory effect and excellent chemical resistance, with reasonable expectation of having a sheet comprising thermoplastic resin, active agent, oily ingredient and thermoplastic elastomer that can be used for medical purposes.

Response to Arguments

13. Applicant's arguments with respect to claims 1-3 and 7-10 have been considered but are moot in view of the new ground(s) of rejection.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

Isis Ghali

ISIS GHALI
PATENT EXAMINER